K030509

MAR 0 4 2003

510(k) Summary

Submitted on behalf of:

Company Name:	**Leonhard Lang GmbH**
Address:	**Archenweg 56** **Innsbruck 6010** **Austria**
Telephone:	**++ 43 / 512 / 33 4 25 7**
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by: Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: 715-549-6035; **fax:** 715-549-5380

Contact person: **Elaine Duncan**

Date prepared: February 13, 2003

Trade Name:	Skintact® ECG Tab Electrode
Common Name:	Disposable ECG Electrodes
Classification Name:	Electrocardiograph (ECG) electrode

SUBSTANTIALLY EQUIVALENT TO: Skintact® ECG Tab Electrodes with KH 06 gel are substantially equivalent to the Skintact® ECG Tab Electrodes with LecTec LT 4900 gel (the manufacterer's predicate - K023920). The additional carbon ink layer added for performance, is substantially equivalent to the MSB electrode (now distributed as Nikotab) originally cleared under K944260.

DESCRIPTION of the DEVICE: Skintact® ECG Tab Electrodes *(and also to be sold under various private label tradenames)* will be offered with KH 06 gel. Skintact® ECG Tab Electrodes with KH 06 gel are self-adhesive, non-sterile, single use disposable electrodes for diagnostic resting ECG. ECG Tab electrodes are composed of a PET tape, carbon ink and Ag/AgCl ink and a conductive gel. These are configured as 10 (ten) electrodes applied to a siliconized transparent PET card, ten cards per pouch.

INDICATIONS FOR USE: Skintact ECG electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include in particular patient ECG surveillance and ECG diagnosis recording. Skintact ECG electrodes are non-sterile and are to be used on intact (uninjured) skin. *(No change to original indication for use.)*

SUMMARY of TESTING: Biocompatibility testing confirms the materials are biocompatible and the change does not introduce new risks. Skintact ECG Tab Electrodes with KH 06 gel were tested in accordance with ANSI/AAMI EC 12:2000. A certification to conformance to this standard has been provided. The testing conducted was: AC impedance; DC offset voltage; Defibrillation overload recovery; Combined offset instability and internal noise; Bias current tolerance. Shelf life of the tab electrodes with KH 06 gel was tested in real-time aging and in accelerated aging. For accelerated aging the electrodes were in an incubator for a time of 3 months with an increased temperature of 40°C. In accelerated shelf life testing the electrodes are subjected to a controlled environment in which one or more extrinsic factors (e.g., temperature, humidity, gas atmosphere, light) is maintained at a higher than normal level. Leonhard Lang has experience for about 20 years of using the current packaging and this ensures all requirements for the 24 months shelf-life of the electrodes. No differences were required for packaging of the solid adhesive electrodes compared to the predicate electrode. For clinical data, three ECG tracings using KH 06 gel electrodes were made. Each tracing contains more than 10 seconds of data. The data demonstrate that ECG Tab electrodes with KH 06 gel provide a reliable signal tracing of consistently high quality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 4 2003

Leonhard Lang, GmbH
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, MN 55082-0560

Re: K030509
Trade Name: Skintact® ECG Tab Electrodes
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: February 13, 2003
Received: February 19, 2003

Dear Ms. Duncan:

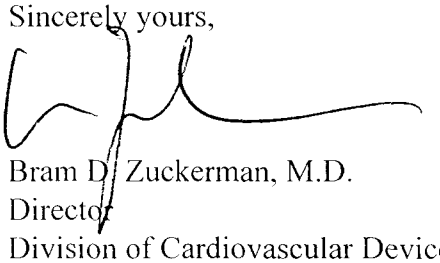
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K030509

Device Name: Skintact® ECG Tab Electrodes

Indications for Use:

Skintact® ECG electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include in particular patient ECG surveillance and ECG diagnosis recording.

Skintact ECG electrodes are non-sterile and are to be used on intact (uninjured) skin.

(Please Do Not Write Below This Line-Continue On Another Page If Needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over -The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030509